APPENDIX 1

Appendix 1: Product Materials And Composition

Commercial Sunscreen Products:

The two commercial sunscreen products used in this study were purchased in spring, 2000 off the shelf from a retail store in Cincinnati, Ohio. One product, code I, is labeled SPF 8 and contains the active ingredients octyl methoxycinnamate (OMC) and oxybenzone (OXY). The other commercial sunscreen product, code J, is labeled SPF 25 and contains OMC, octyl salicylate (OSAL), homosalate (HSAL), and OXY.

Model Sunscreen Ingredients:

The sunscreen active ingredients and excipients used in the prototype sunscreen creams in this study were obtained from the following sources:

- **Sunscreen Actives:**

Abbr.	Trade Name	CTFA/Chemical Name	Manufacturer	Mfg.'s Address
AVO	Parsol 1789	avobenzone	Hoffmann-LaRoche, Inc.	Nutley, NJ
HMS	Eusolex HMS	homosalate	Rona, EM Industries	Hawthorne, NY
OCTO	Neo Heliopan 303	octocrylene	Haarmann & Reimer Corp.	Springfield, NJ
OMC	Parsol MCX	octyl methoxycinnamate	Hoffmann-LaRoche, Inc.	Nutley, NJ
OSAL	Neo Heliopan OS	octyl salicylate	Haarmann & Reimer Corp.	Springfield, NJ
OXY	Univul M40	oxybenzone	BASF	Washington, NJ
PBSA	Parsol HS	phenyl benzimidazole sulfonic acid	Hoffmann-LaRoche, Inc.	Nutley, NJ

- **Excipients:**

Trade Name	CTFA/Chemical Name	Manufacturer	Manufacturer's Address
Amphisol	DEA cetyl phosphate	Givaudan-Roure Corp.	Clifton, NJ
Behenyl Alcohol	behenyl alcohol	Henkel Corp.	Hoboken, NJ
Brij 72	steareth-2	ICI Surfactants	Wilmington, DE
Brij 721	steareth-21	ICI Surfactants	Wilmington, DE
Carbopol 980	carbomer	B. F. Goodrich	Cleveland, OH
Cetyl Alcohol	cetyl alcohol	Procter & Gamble Co.	Cincinnati, OH
Cetyl Palmitate	cetyl palmitate	Henkel	Hoboken, NJ
Disodium EDTA	disodium EDTA	Hampshire Chemical Corp.	Lexington, MA
Emersol 132	stearic acid	Henkel	Hoboken, NJ
Finsolv TN	C12-15 alcohols benzoate	Finetex	Elmwood Park, NJ
Glycerin	glycerin	Van Waters & Rogers	Cincinnati, OH
Kessco IPP	isopropyl palmitate	Stepan Co.	Northfield, IL
Methylparaben	methylparaben	Napp Chemicals Inc.	Saddle Brook, NJ
Pemulen TR-1	acrylates/C10-30 alkyl acrylates crosspolymer	B. F. Goodrich	Cleveland, OH
Propylparaben	propylparaben	Napp Chemicals Inc.	Saddle Brook, NJ
Sepigel 305	polyacrylamide, C13-14 isoparaffins, laureth-7	Seppic	Paris, France
Stearyl Alcohol	stearyl alcohol	Procter & Gamble Co.	Cincinnati, OH
Syncrowax HR-C	tribehenin	Croda	Parsippany, NJ
Triethanolamine	triethanolamine	Dow Chemical	Midland, MI

Model Sunscreen Composition:

Two sets of three prototype sunscreen creams were made and evaluated. Products within each set of creams were based on a similar oil-in-water emulsion matrix, but contained different levels/combinations of sunscreen actives. The matrixes for the two sets of creams were different, however. The general composition of the prototype sunscreen creams was as follows:

Set #1:

Product Phase	Ingredient Name	Level (wt %)
Water Phase	Water	q.s. to 100%
	Glycerin	3
	Triethanolamine	0.71
	Methylparaben	0.25
	Disodium EDTA	0.05
Oil Phase	Isopropyl palmitate	0 - 6
	Cetyl alcohol	1
	Stearic acid	1
	Tribehenin	0.75
	DEA cetyl phosphate	0.75
	Cetyl palmitate	0.5
	Propylparaben	0.15
	Oil soluble sunscreen(s)	16 - 37.5
Thickener	Carbopol 980 Pemulen TR-1	0.25 0.125
		100%

Set #2:

Product Phase	Ingredient Name	Level (wt %)
Water Phase	Water	q.s. to 100%
	Glycerin	2
	Triethanolamine	0.85
	Methylparaben	0.2
	Disodium EDTA	0.1
	PBSA	1.5
Oil Phase	C12-15 alcohols benzoate (TN)	15
	Steareth-21	1.35
	Cetyl alcohol	1
	Stearyl alcohol	1
	Behenyl alcohol	1
	Propylparaben	0.2
	Steareth-2	0.15
	Oil soluble sunscreen(s)	3 - 4
Thickener	Sepigel 305	3.1
		100%

The sunscreen levels in each of the six prototype sunscreen cream compositions are given in the table below. Note that for prototype D, 6% of an oily solvent was added to the formulation because there was not enough oily sunscreen in the prototype to completely solubilize the crystalline oil soluble sunscreens, OXY and AVO.

Code	Matrix	Sunscreen #1	Sunscreen #2	Sunscreen #3	Sunscreen #4	Other
B	Set 1	15% HSAL	5% OSAL	7.5% OMC	10% OCTO	0% Kessco IPP
C	Set 1	15% HSAL	5% OSAL	10% OCTO	6% OXY	0% Kessco IPP
D	Set 1	4% HSAL	5% OCTO	4% OXY	3% AVO	6% Kessco IPP
E	Set 2	1.5% PBSA	4% OMC	-----	-----	-----
F	Set 2	1.5% PBSA	3% OXY	-----	-----	-----
G	Set 2	1.5% PBSA	3% AVO	-----	-----	-----

Model Sunscreen Cream Making Procedure:

Utilizing Good Manufacturing Practices (GMP), the model sunscreen cream formulations above were prepared via conventional emulsification techniques. In general, this involved:

1) Combining all water phase ingredients, including thickeners, and heating to 75-80°C
2) Combining all oil phase ingredients and heating to 75-80°C
3) Slowly adding the oil phase to the water phase while milling
4) Cooling the product to 30°C while stirring, and then pouring the product into suitable containers